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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,574	02/08/2002	Lone Jeppesen	5698.210-US	2406
7590	11/06/2003			EXAMINER TRUONG, TAMTHOM NGO
Reza Green, Esq. Novo Nordisk of North America, Inc. 100 COLLEGE RD. W. PRINCETON, NJ 08540-6604			ART UNIT 1624	PAPER NUMBER S
DATE MAILED: 11/06/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Applicant No. .	Applicant(s)
	10/076,574	JEPPESEN ET AL.
	Examiner	Art Unit
	Tamthom N. Truong	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1, 2, 7, 17, 45-47, and 53-55 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 2, 7, 17, 46, 47, and 53-55 is/are rejected.
- 7) Claim(s) 45 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. 09/419,761.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

This is a divisional application of 09/419,761. The preliminary amendment has been entered. It is noted that the definition of X has been limited to -(CHR<sup>9</sup>)-CH<sub>2</sub>-, -CH=CH-, -(NR<sup>9</sup>)-CH<sub>2</sub>-, -(CHR<sup>9</sup>)-CH<sub>2</sub>-CH<sub>2</sub>-, -CH=(CR<sup>9</sup>)-, -(CO)-(CHR<sup>9</sup>)-, which is the subject matter of Group I of the restriction presented in 09/419,761.

With claims 3-6, 8-16, 18-44, 48-52, and 56-60 cancelled, the remaining claims 1, 2, 7, 17, 45-47, and 53-55 are considered herein.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **New Matter:** Claims 1, 2, 7, 17, 46, 47 and 53-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites the limitations of "*C<sub>1-7</sub>-alkyl, C<sub>2-7</sub>-alkenyl, C<sub>2-7</sub>-alkynyl, C<sub>1-7</sub>-alkoxy*", which has no support in the original disclosure. Although C<sub>1-7</sub>, or C<sub>2-7</sub> falls within the range of C<sub>1-12</sub> disclosed in the specification, there is no preferred

embodiment for selecting a narrower range. Thus, said limitations lack written description as well as enablement.

3. **Lack of Written Description:** Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 53 recites the term “ailments” which has no description as to what diseases would be included.

4. **Utility:** Claim 53 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

A revised utility guidelines require that utilities must be specific, substantial, and credible. By specific, said guidelines call for a particular disorder or disease. In the instant case, the term “ailments” does not point to a particular disease or disorder. By substantial, said guidelines require that utilities must define a “real world” use, and must not constitute further research to identify or reasonably confirm a “real world” context of use. In the instant case, said claim calls for “the treatment of ailments” which is not specific and not substantial as the specification does not appear to list what diseases or disorders are covered by the term “ailments”. Furthermore, many diseases included in said term have no known etiology, and/or no treatment such as schizophrenia, Huntington’s, cancers, and “common cold”, and thus their treatment would require extensive further research. Because applicant has not disclosed any specific and substantial utility for the claimed invention, credibility will not be assessed. See

**Brenner v. Manson**, 148 USPQ 689, and **In re Zeigler**, 26 USPQ 2d 1600, 1603 (Fed. Cir. 1996).

**Lack of Enablement:** Claim 53 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

5. **Enablement:** Claim 54 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no reasonable assurance that such a diverse genus of compounds may be useful in treating a plethora of diseases. That is, there is no correlation between the alleged utility and the screening tests. *In re Fouche*, 169 USPQ 49 (CCPA 1971).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 53 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. The term "ailments" does not have a definite metes and bounds. The specification does not list what diseases or disorders would constitute "ailments". Said term covers many disorders that may not be related to Peroxisome Proliferator-Activated Receptors such as "common cold", asthma, arthritis, osteoporosis, schizophrenia, lupus, cerebral palsy, etc. Thus, it is unclear what disorders are intended.
- b. Claim 54 recites the limitation of "*conditions mediated by nuclear receptors, in particular the Peroxisome Proliferator-Activated Receptors (PPAR)*," which is unclear for two reasons. First, "conditions mediated by" is not clear as to what is meant by the term "mediated". Would said term mean 'activated'? 'deactivated'? or 'inhibited'? It is not clear what biological pathway is intended (i.e., agonizing, or antagonizing). Second, the phrase "in particular" renders the claim indefinite because it is not clear if only PPAR is affected, or other nuclear receptors are also affected. In essence, the phrase "in particular" presents the situation of "broad limitation followed by narrow limitation" see *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989). The Board stated that "broad limitation followed by narrow limitation" can render a claim indefinite by raising a question or doubt as to whether the limitation introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

***Claim Objections***

7. Claim 45 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. A search in the pertinent art does not yield any reference teaching or suggesting the claimed species.

***References cited on PTO-892***

8. The references listed on PTO-892 present the state of the art. While they teach the tricyclic system having azepin, diazepin, or eight-membered nitrogen containing ring, they fail to teach a substituent corresponding to the claimed variable "A".

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (5:00-12:30) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

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September 4, 2003



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